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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,192	10/15/2003	Maurizio Pellecchia	BURNHAM.006A	3780
20995	7590	10/04/2005	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			BURKHART, MICHAEL D	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			1633	

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/686,192

Applicant(s)

PELLECCHIA, MAURIZIO

Examiner

Michael D. Burkhart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 5-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-9 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/15/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                    |                                                                             |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)          |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                | Paper No(s)/Mail Date. <u>9/28/05</u> .                                     |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/16/2004</u> .                                                           | 6) <input type="checkbox"/> Other: ____.                                    |

### **DETAILED ACTION**

Claims 1-9 are pending.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, drawn to a method of detecting binding between a putative ligand and a selectively labeled target molecule, classified in class 435, subclass 7.1.
- II. Claims 5-9, drawn to methods of producing a selectively labeled target molecule, classified in class 435, subclass 107.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I and II are biologically and functionally distinct from each other and thus one does not render the other obvious. The methods of Groups I and II comprise steps which are distinct from each other: the steps of generating NMR spectra, forming a mixture with a putative ligand, and comparing NMR spectra of Group I are not found in Group II and the step of culturing a transformed cell containing an expression vector of Group I is not found in Group II. The end result of the methods are different, Group I detects a binding interaction by comparison of NMR spectra and Group II produces a labeled target molecule. Thus, the operation, function and effects of these different methods are distinct from each other and therefore are capable of supporting separate patents.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

During a telephone conversation with Darryl Steensma on 9/28/2005 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-4. Affirmation of this election must be made by applicant in replying to this Office action. Claims 5-9 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(a) as being anticipated by Pellecchia et al (Feb. 2002, J. Biomol. NMR). The claims recite a method of detecting binding between a ligand and a selectively labeled target protein including at least one labeled tryptophan residue by generating NMR spectra of the target molecule before and after mixture with the ligand, then comparing the spectra. The tryptophan may be labeled with nuclei selected from the group of  $^1\text{H}$ ,  $^{13}\text{C}$ ,  $^{15}\text{N}$ , and  $^{19}\text{F}$ . The selectively labeled target molecule may be any of those proteins or polypeptides listed in claims 3 and 4.

Pellecchia et al disclose a method of selectively labeling the bacterial enzyme DHPR using  $^{13}\text{C}/^1\text{H}$  labeled Met, Ile, and Thr residues (page 167, second column, first full paragraph). This labeled DHPR was used to generate NMR spectra with and without the ligand PDC, and the

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spectra were compared (Fig. 1C and 1D). Also disclosed is that Tryptophan (Trp) residues could also be selectively labeled with  $^{13}\text{C}/^1\text{H}$  (page 171, paragraph bridging first and second columns).

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Fesik et al (U.S. patent 5,698,401, 1997, cited by applicants). The claims are described above. Regarding the term "selectively labeled", it is herein interpreted as defined by applicants in paragraph [0021] of the publication of the instant application: "Selective labeling is defined as labeling substantially every occurrence of at least one particular amino acid throughout a polypeptide sequence". Thus, regarding the instant claims, this term is considered to encompass polypeptides in which tryptophan, and other amino acids, are labeled.

Fesik et al disclose the labeling of stromelysin (and other proteins) with  $^{15}\text{N}/^1\text{H}$  and obtaining NMR spectra before and after addition of a test compound, and residues that show significant changes are indicated (Fig. 4, Fig. 9, and column 4, lines 41-48). Stromelysin contains at least two tryptophan residues (see SEQ ID NO:1, residues 10 and 42, of the Sequence listing) which are considered to be labeled, absent evidence to the contrary. Furthermore, one tryptophan was found to be one of the residues associated with a chemical shift upon ligand binding (see column 16, lines 34-49).

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael D. Burkhart  
Examiner  
Art Unit 1633

**CELIAN QIAN**  
**PATENT EXAMINER**

A handwritten signature in black ink, appearing to read 'C. Qian', with a long horizontal stroke extending to the right.